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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/047,749	10/23/2001	Paul Lehmann	9524	7514

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EXAMINER
NICHOLS, CHRISTOPHER J

ART UNIT	PAPER NUMBER
1647	4

DATE MAILED: 01/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/047,749	LEHMANN, PAUL	
	Examiner	Art Unit	
	Christopher Nichols, Ph.D.	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 March 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *15-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *15-27* are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. *09/381248* .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Status of Application, Amendments, and/or Claims

1. The Preliminary Amendment of 23 October 2001 (Paper No. 2) has been entered in full. Claims 1-14 are canceled. Claims 15-27 have been added. Claims 15-27 are under examination.

2. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1647, Examiner Christopher Nichols.

Information Disclosure Statement

3. The information disclosure statement filed 21 March 2002 (Paper No. 3) fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because citations 4B (WO 97/09996) and C2 (Wick et al., 1996) are not in the English language. The citations WO 97/09996 and Wick et al. (1996) have been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of this citation in the English language will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609 ¶ C(1).

4. The information disclosure statement filed 21 March 2001 (Paper No. 3) fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. Citations C9 (Breymann et al.) and C10 (Goodnough et al.) were not present, therefore these citations (C9 and C10) were not considered. Applicant is advised that the

date of any re-submission of this citation in the will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609 ¶ C(1).

Specification

5. The Specification is objected to because of the following informalities: delete unnecessary abbreviation "ca." (pp. 2 line 3, pp. 3 line 16, pp. 4 line 11, pp. 6 line 11, pp. 8 lines 4 and 6, pp. 15 line 23); delete space between "20 %" (pp. 5 line 12); misspelled word "ifon" (pp. 9 line 10); misspelled word "ar" (pp. 9 line 18); delete "etc" (pp. 10 line 31; pp. 16 line 10); misspelled word "iron_ions" (pp. 12 line 34); misspelled word "lypophili_ate" (pp. 14 line 11); misused word "born" should be "bore" (pp. 14 line 33); misspelled word "to_100,000" (pp. 16 line 21); misspelled word "in_order" (pp. 22 line 3);. Appropriate correction is required.

6. The abstract of the disclosure is objected to because it is two paragraphs long. Please limit the abstract to one paragraph. Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 15-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. Claims 15-27 are vague and indefinite in that those claims recite the terms: "in an amount of ___ U to ___ U". It is unclear what the aforementioned term refers to, as the metes and bounds of the aforementioned claims cannot be determined as the specification, claims, and art do not recognize what units, unit amounts, quantitative measures (i.e. grams, kilograms, or kilograms per cc) the generic term "U" defines, which are units of measured associated with conventional dosages in such preparations (Means, 1995; Grützmacher et al., 1992; Adamson, 1996; US 5541158; EPO 0 286 439 A1; MacDougall, 1994; Taylor et al., 1996).

9. Claim 24 is vague and indefinite in that it recites the terms: "wherein the Fe(III) complex has a molecular weight of 30,000-100,000 D." It is unclear what the aforementioned term refers to, as the metes and bounds of the aforementioned claims cannot be determined as the specification, claims, and art do not recognize that molecular weight of Fe(III) salts or complexes, such as those defined by the claimed invention, could be defined in Dalton units. The iron salts complexes of the claimed invention are not attached to large biological molecules, such as proteins, which might be defined in Dalton units of measure, but instead complexes or salts that would be measured in molecular weight units of g/M or grams, for instance, conventionally associated with such iron complexes or salts (Means, 1995; Grützmacher et al., 1992; Adamson, 1996; US 5541158; EPO 0 286 439 A1; MacDougall, 1994; Taylor et al., 1996).

Claim Rejections
Double Patenting

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686

F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claims 15-27 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-34 of U.S. Patent No. 6333306 in view of Mercuriali and Inghilleri, 1995. Although the claims are not identical, they are not patentably distinct from each other because the claims of US 6333306 describes a method for the treatment of hemodialysis patients or patients exhibiting anemia, comprising administering to a patient in need of such treatment effective amounts of erythropoietin and a physiologically tolerable iron preparation, wherein the pharmaceutical combination preparation contains about 2,000 to 7,000 U of erythropoietin and a quantity of iron preparation equivalent to about 1-20 mg of iron ions, wherein the erythropoietin and the iron preparation are administered both in the correction phase and the maintenance phase of iron therapy, wherein the iron doses are, independently, 1-20 mg/week in the correction phase and the maintenance phase and wherein the erythropoietin doses are, independently, up to 15,000 U/week in the correction phase and the maintenance phase thus meeting the limitations of claim 15 (Col. 12 claims 1-5).

12. Regarding iron dosages, the art recognizes that it is important to provide adequate supplemental iron during erythropoietin treatment. Mercuriali and Inghilleri (1995) provide a method by which these dosages can be determined for the treatment thus meeting the limitations of Claims 15-27 (pp. 73 "Iron Supplementation Strategies").

13. Regarding iron preparations and iron complexes, US 6333306 teaches the use of physiologically tolerable iron salts or iron complex compounds include and iron(II) saccharate complex. Also, the preferred iron preparations are Fe(III) complexes, especially those having a molecular weight of between 30,000 and 100,000 D thus meeting the limitations of claims 22-27 (Col. 6-8).

14. It would have been obvious to the person of ordinary skill in the art at the time the invention was made to use adjust the amounts of erythropoietin and iron supplements to improve erythropoietin therapy (Mercuriali and Inghilleri, 1995).

15. A person of ordinary skill in the art at the time of the invention could reasonably expect success because the combination of iron supplements and erythropoietin are known in the art at the time of the invention (Mercuriali and Inghilleri, 1995: 68 "Dosage of r-HuEPO").

16. The person of ordinary skill in the art would have been motivated to make those modifications because of the danger of iron toxicity and the need to carefully tailor iron administration during erythropoietin therapy to insure sufficient iron is present to meet the demands of increased hematopoiesis. The modification of the amounts and administration regiment at the time of the invention was seen as a desirable method to improve the effectiveness of erythropoietin therapy.

Summary

17. Claims 15-27 are hereby rejected.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher Nichols, Ph.D. whose telephone number is 703-305-3955. The examiner can normally be reached on Monday through Friday, 8:30AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, Ph.D. can be reached on 703-308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications. The fax phone numbers for the customer service center is 703-872-9305.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Elizabeth C. Kemmerer

CJN
December 16th, 2002

ELIZABETH KEMMERER
PRIMARY EXAMINER